K101203

SEP 10 2010

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: April 23rd, 2010

Device Name

Proprietary names: Tina-Quant Albumin Gen. 2

Common names: Albumin Gen. 2 assay

Regulation: 21 CFR 866.5040

Classification names: Albumin Immunological Test System

Product codes: DCF

Device Description

The Tina-quant Albumin Gen. 2 assay employs an immunoturbidimetric test in which anti-albumin antibodies react with the antigen in the sample to form antigen/antibody complexes which, following agglutination are determined turbidimetrically.

Intended use

Immunoturbidimetric assay for the quantitative, in vitro determination of albumin in human urine, serum, plasma and CSF on Roche/Hitachi cobas c systems.

Indications for Use

The Tina-quant Albumin Gen. 2 assay is an immunoturbidimetric assay intended for the quantitative determination of albumin in serum, plasma, urine, and CSF on Roche/Hitachi cobas c systems. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

Substantial equivalence

The urine application of the Tina-quant Albumin Gen. 2 assay is substantially equivalent to the Hitachi Microalbumin urine assay. The Hitachi Microalbumin urine assay was cleared under K932950.

The Serum/plasma and CSF applications of the Tina-quant Albumin Gen. 2 assays are substantially equivalent to the Behring Nephelometric method cleared in K972929.

Substantial equivalence – comparison

Feature	Tina-quant Albumin Gen. 2 Assay Urine Application	Predicate Device: Hitachi Microalbumin Urine Assay (K932950)
Intended Use	In vitro test for the quantitative determination of albumin in human urine, serum, plasma and CSF (albumin CSF/serum ratio) on Roche/Hitachi cobas c systems.	For the quantitative determination of low levels of albumin in urine (Microalbumin, MAU).
Assay Protocol	Immunoturbidimetric	Same
Sample Type	Urine	Same
Labeled Instrument Platform	Roche/Hitachi cobas c analyzer – cobas c501	Boehringer Mannheim/Hitachi 747 analyzer
Calibrator	C.f.a.s. PUC	Microalbumin calibrators (included in kit)
Calibration Frequency	Calibrate after reagent lot change and as required following quality control procedures	Perform full calibration every two weeks.
Controls	Precinorm PUC and Precipath PUC or Precinorm Protein and Precipath Protein	Precinorm Albumin and Precipath Albumin
Reagent Stability	On-board in use: 12 weeks at 2-8 Deg. C	On-board in use: 4 weeks at 2-12 Deg. C

Measuring Range	c501: 12-400 mg/L	3 mg/L up to the value of the highest calibrator *Note: calibrator values were lot specific. In one representative lot, values (mg/L) were:* Cal 3a: 0.0 Cal 3b: 10.5 Cal 3c: 62.6 Cal 3d: 154.0 Cal 3e: 347.0
Precision	<u>cobas c501:</u> Repeatability (Within-run) (mg/L): Mean = 30.7, SD = 0.2, CV = 0.8% Mean = 108, SD = 1, CV = 0.7% Mean = 14.3, SD = 0.2, CV = 1.6% Mean = 252 mg/L, SD = 4, CV = 1.6% Intermediate Precision (Total) (mg/L): Mean = 31.2, SD = 0.5, CV = 1.7% Mean = 105, SD = 1, CV = 1.2% Mean = 13.6, SD = 0.4, CV = 2.8% Mean = 60.6, SD = 1.4, CV = 2.3%	Within-run (mg/L): Mean = 9.0, SD = 0.29, CV = 3.2% Mean = 22.1, SD = 0.30, CV = 1.4% Mean = 81.1, SD = 0.67, CV = 0.8% Total (mg/L): Mean = 9.0, SD = 0.92, CV = 10.1% Mean = 22.1, SD = 1.15, CV = 5.2% Mean = 81.1, SD = 0.78. CV = 1.0%
Analytical Sensitivity	Limit of Blank (LoB) =2 mg/L Limit of Detection (LoD) =3 mg/L Limit of Quantitation (LoQ) =12 mg/L	Lower Detection Limit = 3 mg/L
Analytical Specificity	No interference was found at common therapeutic concentrations using common drug panels. Due to the antigen excess check reagent R3, no unflagged high-dose hook effect will occur up to an albumin concentration of 40000 mg/L.	No interference was observed from 18 common drugs.

Interferences	*Criterion: Recovery within ± 10%* Icterus: no significant interference up to an I index of 50 (approximate conjugated bilirubin concentration: 50 mg/dL) Hemolysis: No significant interference up to an H index of 400 (approximate hemoglobin concentration: 400 mg/dL) No interference by acetone ≤ 60 mmol/L, ammonia chloride ≤0.11 mol/L, calcium ≤40 mmol/L, Creatinine ≤0.18 mol/L, γ-globulin ≤500 mg/L, glucose ≤0.19 mol/L, urea ≤0.8 mol/L, uric acid ≤5.95 mmol/L and urobilinogen ≤378 umol/L.	No significant interference observed from calcium levels up to 100 mg/dL. Icterus: no significant interference from bilirubin up to 25 mg/dL. Hemolysis: Hemoglobin levels >300 mg/dL cause significant positive interference. Lipemia (Intralipid): No significant interference up to an L index of 200. There is poor correlation between the L index (corresponds to turbidity) and triglyceride concentration.
Expected Values	2nd morning urine: Adults: <20 mg albumin/g creatinine or <2.26 g albumin/mol creatinine Children (3-5 years): <20 mg/L albumin <37 mg albumin/g creatinine 24 hour urine: <20 mg/L <30 mg/24 h	2nd morning urine: Adults: same Children (3-5 years): same 24 hour urine: Microalbuminuria: 30-300 mg albumin/24 hr
Method Comparisons	A comparison of the Roche Tina-quant Albumin Gen. 2 assay on the c501 analyzer(x) with the Hitachi Microalbumin assay on the Hitachi 917 analyzer (K953239) (y) gave the following correlation: Passing Bablock: $y = 1.023x + 3.64$ mg/L, $\tau = 0.984$ Linear Regression: $y = 1.028x - 4.13$ mg/L, $r = 0.999$ n = 125 Sample concentrations were between 12.3 and 386 mg/L	

Substantial equivalence – comparison

Feature	Tina-quant Albumin Gen. 2 Assay Serum/Plasma Application	Predicate Device: Behring N Antiserum to Human Albumin Assay (K972929)
Intended Use	In vitro test for the quantitative determination of albumin in human urine, serum, plasma and CSF (albumin CSF/serum ratio) on Roche/Hitachi cobas c systems.	In vitro diagnostic reagent for the quantitative determination of albumin, prealbumin (transthyretin) and retinol-binding protein (RbP) in human serum as well as of albumin in human urine and cerebrospinal fluid (CSF) using the BN Systems.
Assay Protocol	Immunoturbidimetric	Same
Sample Type	Serum Plasma: Li-heparin and K_2-EDTA	Serum
Labeled Instrument Platform	Roche/Hitachi cobas c analyzer – cobas c501	BN Systems
Calibrator	C.f.a.s. PUC	N Protein Standard SL (human)
Calibration frequency	Full calibration is recommended after reagent lot change and as required following quality control procedures.	Same
Controls	Precinorm PUC and Precipath PUC or Precinorm Protein and Precipath Protein	N/T Protein Controls SL/L, M and H or N/T Protein Control LC
Measuring Range	c501: 3 – 101 g/L	Reference curves are generated by multi-point calibration. Serial dilutions on N Protein Standard SL are automatically prepared by the instrument using N Diluent.

Precision	<u>cobas c501:</u> Repeatability (Within-run) (mg/L): Mean = 39.9, SD = 0.5, CV = 1.2% Mean = 66.6, SD = 1.4, CV = 1.2% Mean = 27.6, SD = 0.4, CV = 1.3% Mean = 62.5 mg/L, SD = 0.9, CV = 1.5% Intermediate Precision (Total) (mg/L): Mean = 42.3, SD = 0.9, CV = 2.0% Mean = 70.5, SD = 1.6, CV = 2.2% Mean = 7.78, SD = 0.74, CV = 9.5% Mean = 36.2, SD = 0.7, CV = 2.1%	Intra-assay (g/L): Mean: 46.5; CV: 4.3% Inter-assay (g/L) Mean: 44.7; CV: 4.4%
Analytical Sensitivity	Limit of Blank (LoB) = 1 g/dL Limit of Detection (LoD) = 2 g/dL Limit of Quantitation (LoQ) = 3 g/dL	Established by the lower limit of the reference curve and depends therefore upon the concentrations of the proteins in the N Protein Standard SL.
Analytical Specificity	No interference was found at common therapeutic concentrations using common drug panels.	No interference from commonly used drugs is known.
Interferences	*Criterion: Recovery within ± 10%* Icterus: no significant interference up to an I index of 60 (approximate conjugated bilirubin concentration: 60 mg/dL) Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 1000 mg/dL) Lipemia: No significant interference up to an L index of 1500 (approximate Intralipid concentration: 1500 mg/dL). There is poor correlation between the Intralipid concentration (corresponds to turbidity) and triglycerides concentration. Rheumatoid factors ≤ 1200 IU/mL do not interfere.	Turbidity and particles in the sample may interfere with the determination. Therefore, samples containing particles must be centrifuged prior to testing. Bovine serum albumin in the sample (e.g. control sample) may disturb the determination.

Expected Values	Reference Range Study: Adults: 3.56-4.61 g/dL Consensus Values: Adults: 3.5 – 5.2 g/dL Reference Intervals according to Tietz: Newborns 0-4d: 2.8 – 4.4 g/dL Children 4d-14yr: 3.8 – 5.4 g/dL Children 14-18yr: 3.2 – 4.5 g/dL	Adults: 35.0 – 52.0 g/L
Method Comparison	A comparison of the Roche Tina-quant Albumin Gen. 2 assay on the cobas c501 analyzer(x) with the nephelometric Albumin test gave the following correlation: Passing Bablock: $y = -0.1320 + 0.9600x$, $\tau = 0.919$ Linear Regression: $y = -0.0095 + 0.9572x$, $r = 0.993$ $n = 77$ Sample concentrations were between 5.70 and 100 g/L	

Substantial equivalence – comparison

Feature	Tina-quant Albumin Gen. 2 Assay CSF Application	Predicate Device: Behring N Antiserum to Human Albumin Assay (K972929)
Intended Use	In vitro test for the quantitative determination of albumin in human urine, serum, plasma and CSF (albumin CSF/serum ratio) on Roche/Hitachi cobas c systems.	In vitro diagnostic reagent for the quantitative determination of albumin, prealbumin (transthyretin) and retinol-binding protein (RbP) in human serum as well as of albumin in human urine and cerebrospinal fluid (CSF) using the BN Systems
Assay Protocol	Immunoturbidimetric	Same
Sample Type	CSF	Same
Labeled Instrument Platform	Roche/Hitachi analyzer – cobas c501	BN Systems

Calibrator	C.f.a.s. PAC	N Protein Standard SL (human)
Controls	Commercially available control	N/T Protein Controls SL/L, M and H or N/T Protein Control LC
Measuring Range	c501: 95 - 3000 mg/L	Reference curves are generated by multi-point calibration. Serial dilutions on N Protein Standard SL are automatically prepared by the instrument using N Diluent.
Precision	Repeatability (Within-run) (mg/L): Mean = 99.2, SD = 1.4, CV = 1.4% Mean = 174, SD = 3, CV = 1.7% Mean = 383, SD = 4, CV = 1.0% Mean = 454 mg/L, SD = 4, CV = 0.8% Intermediate Precision (Total) (mg/L): Mean = 91.0, SD=2.9, CV = 3.2% Mean = 389, SD = 7, CV = 1.7% Mean = 166, SD = 4, CV = 2.3% Mean = 366, SD = 5, CV = 1.3%	Not specified for CSF
Analytical Sensitivity	Limit of Blank (LoB) = 20 mg/L Limit of Detection (LoD) = 36 mg/L Limit of Quantitation (LoQ) = 95 mg/L	Established by the lower limit of the reference curve and depends therefore upon the concentrations of the proteins in the N Protein Standard SL.
Analytical Specificity	No interference was found at common therapeutic concentrations using common drug panels.	No interference from commonly used drugs is known.

Interferences	*Criterion: Recovery within ± 10%* Hemolysis: No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 1000 mg/dL) Icterus: No significant interference up to an I index 60 (approximate conjugated and unconjugated bilirubin concentration: 600 mg/L) High dose hook-effect: Using the prozone check, no false result without a flag was observed up to an albumin concentration of 30000 mg/L.	Not specified for CSF.
Expected Values	Albumin in CSF: 3 months to 4 year: < 450 mg/L > 4 years: 100 – 300 mg/L	Albumin in CSF: up to 350 mg/L
Method Comparisons	A comparison of the Roche Tina-quant Albumin Gen. 2 assay on the cobas c501 analyzer(x) with the nephelometric Albumin test gave the following correlation: Passing Bablock: $y = 1.000x - 8.75$ mg/L, $\tau = 0.936$ Linear Regression: $y = 0.991x + 0.301$ mg/L, $r = 0.992$ n = 85 Sample concentrations were between 115 and 2640 mg/L	

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food & Drug Administration
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Silver Spring, MD 20993

Re: k101203
Trade Name: Tina-quant albumin gen 2
Regulation Number: 21 CFR §866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DCF
Dated: September 9, 2010
Received: September 10, 2010

SEP 10 2010

Dear Ms. Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

K101203

510(k) Number (if known): k101203

SEP 10 2010

Device Name: Tina-quant Albumin Gen. 2

Indications for Use:

The Tina-quant Albumin Gen. 2 assay is an immunoturbidimetric assay intended for the quantitative determination of albumin in serum, plasma, urine, and CSF on Roche/Hitachi cobas c systems. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101203